

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JENNIFER TUNG et al.,
Plaintiffs,

-v-

BRISTOL-MYERS SQUIBB
COMPANY et al.,
Defendants.

18-CV-1611 (JPO)

OPINION AND ORDER

J. PAUL OETKEN, District Judge:

In 2014, Defendant Bristol-Myers Squibb Company announced a clinical trial to test the efficacy of one of its newest anticancer drugs. The trial failed, which precipitated a drop in the company's stock price. Plaintiffs now bring this putative shareholder class action, alleging that public statements by Bristol-Myers and its officers mischaracterized the experimental design of the trial, thereby overstating the likelihood of the trial's success. The plaintiffs bring claims under Rule 10b-5 and Sections 10(b), 20(a), and 20A of the Securities Exchange Act. For the reasons that follow, the claims are dismissed.

I. Background

The following facts are taken from the operative complaint and, for purposes of this motion to dismiss, are assumed to be true.

Defendant Bristol-Myers Squibb Company is a pharmaceutical company whose product portfolio includes anticancer drugs. (Dkt. No. 44 ("Compl.") ¶ 24.) During the relevant class period — January 27, 2015 to October 9, 2016 (Compl. at 1) — the company's officers included Defendants Michael Giordano, Fouad Namouni, Francis M. Cuss, Giovanni Caforio, Lamberto Andreotti, and Charles A. Bancroft (Compl. ¶¶ 25–29, 32).

Prior to and during the class period, Bristol-Myers began focusing significant attention on immuno-oncology, a relatively new field of cancer research that explores the ability of the body's own immune system to fight cancer. (Compl. ¶ 35.) In particular, Bristol-Myers began developing the drug Opdivo (also called nivolumab), which belongs to a class of immunotherapy drugs known as "checkpoint inhibitors." (Compl. ¶¶ 38, 42.) Immune "checkpoints" are cellular mechanisms that prevent the body's immune system from attacking healthy cells. (Compl. ¶ 37.) One particular immune checkpoint centers around PD-L1, a protein that, when present on healthy cells, prevents the immune system from attacking them (specifically, by binding to PD-1, a protein present on the immune system's T-cells, which are attack cells). (*Id.*) But cancer cells can take advantage of this checkpoint by themselves expressing the PD-L1 protein, which disables the body's immune system from attacking and allows the cancer to grow unchecked. (*Id.*) PD-1 checkpoint inhibitors are drugs that inhibit cancer cells from doing so, causing the immune system to attack the cancer cells. (*Id.*)

It follows that the efficacy of PD-1 checkpoint inhibitors depends in part on the level at which a patient's cancer cells express PD-L1. (Compl. ¶ 49.) The lower the natural rate of PD-L1 expression by cancer cells, the less likely it is that a drug inhibiting PD-L1 expression will make any difference. (*See* Compl. ¶¶ 48–49.) Thus, when designing a study to test the efficacy of a PD-1 checkpoint inhibitor, a company must first determine how high a patient's expression of PD-L1 must be to qualify for inclusion in the study. In doing so, the company faces a trade-off: The higher the cut-off, the more likely that the study will yield positive results. (*See, e.g.*, Compl. ¶ 81.) But the lower the cut-off, the more patients are opened up for potential treatment. (*See, e.g.*, Compl. ¶ 98.)

In January 2014, Bristol-Myers announced a new clinical trial, Checkmate-026, that sought to determine whether Opdivo would outperform chemotherapy as a treatment for non-small cell lung carcinoma, the most common type of lung cancer. (Compl. ¶¶ 61–62.) An initial description stated that “the purpose of this study is to show that [Opdivo] will improve [outcomes] in subjects with *strongly* Stage IV or Recurrent PD-L1+ non-small cell lung cancer when compared to chemotherapy.” (Compl. ¶ 64 (emphasis omitted).) Similar representations were made elsewhere. (See, e.g., Compl. ¶¶ 125–30.) Bristol-Myers did not, however, clarify how much PD-L1 expression was required for a patient to “strongly” express PD-L1. (See Compl. ¶ 71.)

In May 2014, Merck, a rival pharmaceutical company, published a study (called Keynote-024) testing the efficacy of its own PD-1 checkpoint inhibitor drug, Keytruda. (Compl. ¶¶ 67–68.) Merck limited Keynote-024’s eligibility to those patients with “PD-L1 *strong* expressing tumor.” (Compl. ¶ 68 (emphasis added).) Merck disclosed that its definition of “strong” included only those patients in which at least 50% of tumor cells expressed PD-L1. (*Id.*)

On August 5, 2016, Bristol-Myers announced that Checkmate-026 had failed to demonstrate that Opdivo outperformed chemotherapy. (Compl. ¶ 92.) Bristol-Myers also revealed that the cut-off for the targeted patient population — *i.e.*, patients that “strongly” expressed PD-L1 — was 5%. (*Id.*) In response to this news, Bristol-Myers’s stock price dropped approximately 16% from August 4 to August 5. (Compl. ¶ 100.)

On October 9, 2016, Bristol-Myers further revealed that the study’s design precluded the researchers from reaching any conclusions about the efficacy of Opdivo for patients whose expression of PD-L1 were higher than 5%. (Compl. ¶ 105.) As a result, Bristol-Myers “had no

means under accepted statistical methodologies of finding a significant difference between the performance of Opdivo and chemotherapy.” (Compl. ¶ 108.) In response to this news, Bristol-Myers’s stock price dropped more than 10% from October 7 (the nearest trading day) to October 10. (Compl. ¶ 110.)

Lead Plaintiff Arkansas Public Employees Retirement System is a public pension fund that provides retirement benefits for qualified public employees of the state of Arkansas. (Compl. ¶ 21.) Lead Plaintiff Louisiana Sheriffs Pension & Relief Fund is a governmental retirement plan providing benefits to active and retired employees of the sheriff’s offices of Louisiana. (Compl. ¶ 22.) Both lead plaintiffs purchased Bristol-Myers common stock during the class period and suffered losses. (Compl. ¶¶ 21–22.)¹

Plaintiffs bring suit against Bristol-Myers and various of its officers, alleging violations of section 10(b) of the Securities Exchange Act and Rule 10b-5. (Compl. ¶¶ 225–32.) Based on that alleged primary violation, Plaintiffs also allege that certain officers violated sections 20(a) and 20A of the Act. (Compl. ¶¶ 233–47.)

II. Legal Standard

To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must plead sufficient factual allegations “to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible if the well-pleaded factual allegations of the complaint, presumed true, permit the court to “draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

¹ The original plaintiff, Jennifer Tung, was not certified as a class representative. (See Dkt. No. 42 at 2.)

“Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss.” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). The heightened pleading requirements are set forth in Rule 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737. A securities fraud complaint based on misrepresentations must “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000) (internal quotation marks omitted).

Plaintiffs have alleged violations of section 10(b) of the Securities Exchange Act, Rule 10b-5, and sections 20(a) and 20A of the Act. For the reasons that follow, each of the claims is dismissed.²

A. Claims Under Section 10(b) and Rule 10b-5

To state a claim under section 10(b) and Rule 10b-5, “a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008).

The requisite scienter is “an intent to deceive, manipulate, or defraud.” *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001) (quoting *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 168 (2d Cir. 2000)). Further — because a complaint asserting securities fraud must comply with the

² Because the motion to dismiss is granted, Defendants’ motion for oral argument on the motion to dismiss (Dkt. No. 64) is denied as moot.

heightened pleading requirements imposed by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act — a plaintiff stating a claim under section 10(b) and Rule 10b-5 must raise a “strong inference” of scienter by alleging facts showing either “(1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness.” *ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009).

Here, Plaintiffs have not shown either to be true. Thus, Plaintiffs have failed adequately to plead scienter, which means that their claims under section 10(b) and Rule 10b-5 must be dismissed.

1. Fraudulent Motive and Opportunity

In order to raise a “strong inference” of scienter under the “motive and opportunity” prong, the plaintiffs must allege that Bristol-Myers or its officers stood to “benefit[] in some concrete and personal way from the purported fraud.” *Novak v. Kasaks*, 216 F.3d 300, 307–08 (2d Cir. 2000). Crucially, “[m]otives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute ‘motive’ for purposes of this inquiry.” *ECA*, 553 F.3d at 198.

Plaintiffs adduce two motives to commit fraud, but neither suffices. The first is Defendants’ motive “to protect competitively sensitive information.” (Dkt. No. 57 at 29.) But the protection of proprietary information is the quintessence of a “generalized” business motive. *See Chill v. Gen. Electric Co.*, 101 F.3d 263, 268 (2d Cir. 1996). Plaintiffs allege no “concrete benefits” that would accrue to the Defendants beyond “maintain[ing] the appearance of corporate profitability[] or of the success of an investment.” *Id.* If scienter could be pleaded on this basis alone, “virtually every company in the United States that experiences a downturn in stock price

could be forced to defend securities fraud actions.” *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995).

The second is the Defendants’ motive to sell stock “while the price was artificially inflated as a result of [their] intentional manipulation of the market[.]” (Dkt. No. 57 at 29.) As evidence, the complaint cites stock sales by Defendants Andreotti, Bancroft, Caforio, and Cuss. (Compl. ¶ 214.) Such allegations, however, can establish fraudulent motive only if Plaintiffs first demonstrate that the stock sales were “unusual” or suspicious. *Acito*, 47 F.3d at 54. They have not done so. As an initial matter, the complaint entirely fails to allege that Defendants Giordano or Namouni sold any shares during the relevant period (*see* Compl. ¶ 214), which substantially undermines Plaintiffs’ claim that Defendants were motivated by an intent to engage in insider trading, *see Acito*, 47 F.3d at 54; *see also San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 814 (2d Cir. 1996) (“[T]he fact that other defendants did not sell their shares during the relevant class period sufficiently undermines plaintiffs’ claim regarding motive.”); *In re eSpeed, Inc. Sec. Lit.*, 457 F. Supp. 2d 266, 291 (S.D.N.Y. 2006) (“[T]he dispositive factor is that other insiders, including the other two individual defendants, did not sell during the putative class period.”).

And even for the Defendants who did sell shares, the complaint lists only stock sales while excluding stock purchases. (*See* Compl. ¶ 215.) As a result, Plaintiffs have “demonstrate[d] only gross proceeds without identifying net profits.” *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011). And “proceeds alone say nothing about a seller’s motive.” *Id.*; *see also In re eSpeed*, 457 F. Supp. 2d at 290 (finding complaint deficient because it “d[id] not disclose whether [defendants] made any *profit* from the sales”). Moreover, each of these Defendants kept constant or *increased* his ownership of Bristol-Myers during the class

period. (Dkt. No. 52 at 29 & nn.39–40.) The fact that the Defendants “*increased* their [stock] holdings during the Class Period [is] wholly inconsistent with fraudulent intent.” *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004).

In light of these considerations, the Court concludes that Plaintiffs have failed to adequately allege a fraudulent motive.

2. Conscious Misbehavior or Recklessness

Plaintiffs who have failed to demonstrate fraudulent motive may nonetheless raise a “strong inference” of scienter under the “conscious misbehavior or recklessness” prong, “though the strength of the circumstantial allegations must be correspondingly greater” if there was no underlying motive to commit fraud. *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (quoting *Beck v. Mfrs. Hanover Trust Co.*, 820 F.2d 46, 50 (2d Cir. 1987)). To survive dismissal, the complaint must plead behavior which is “highly unreasonable” and which represents “an extreme departure from the standards of ordinary care.” *Id.* (quoting *In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000)). In other words, the pleaded facts must indicate “a state of mind approximating actual intent.” *Novak*, 216 F.3d at 312 (internal quotation marks omitted).

Plaintiffs’ allegations fall far short of that demanding standard. Even if the Court assumes the existence of a fixed usage of “strong” that excluded a PD-L1 expression cut-off of 5%, the complaint still fails to plead facts giving rise to a strong inference that the fixed usage “was either known to the defendants or so obvious that the defendants must have been aware of it” at the time of the alleged misrepresentations. *ECA*, 553 F.3d at 198 (quoting *Novak*, 216 F.3d at 308).

As evidence that the Defendants were aware of the industry usage, Plaintiffs first cite general facts about Bristol-Myers’s leading position in the immuno-oncology market. (See Dkt. No. 57 at 33–34.) Plaintiffs also cite general assurances from various Defendants that Bristol-

Myers had a “depth of understanding” about “the role of PD-L1 expression.” (Dkt. No. 57 at 33–34 (quoting Compl. ¶ 160).) And Plaintiffs argue that the Defendants must have been aware of “industry practices” because they were “inextricably involved in setting” them. (Dkt. No. 57 at 34 n.19.) These allegations do not suffice. “Where plaintiffs contend defendants had access to . . . facts [contradicting their public statements], they must specifically identify the [source of] this information.” *Novak*, 216 F.3d at 309. “Conclusory allegations of a[] . . . defendant’s skill or experience” do not suffice “unless it is specifically shown how or why the [defendant] should have believed the [misrepresentations] to be inaccurate.” *O’Brien v. Price Waterhouse*, 740 F. Supp. 276, 282 (S.D.N.Y. 1990). Plaintiffs’ conclusory allegations of knowledge do not suffice.³

Plaintiffs next argue that Bristol-Myers’s conduct proves that Defendants were aware of the industry standard. Plaintiffs cite prior studies in which Bristol-Myers employed a 5% cut-off to define mere “positive” expression. (Dkt. No. 57 at 27 (citing Compl. ¶ 198).) These prior studies, they argue, contradict Bristol-Myers’s current position that a 5% cut-off can be used to

³ In dueling footnotes (*see* Dkt. No. 52 at 34 n.45; Dkt. No. 57 at 32 n.17; Dkt. No. 62 at 19 n.59), the parties dispute the applicability of the core operations doctrine, which permits an inference of scienter when “[a] defendant ma[k]es false or misleading statements” if “those statements concern[] the core operations of the company.” *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004).

As an initial matter, it is “questionable” whether the core operations doctrine is good law after the enactment of the Private Securities Litigation Reform Act. *Glaser*, 772 F. Supp. 2d at 596 n.17; *see also In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 353 (S.D.N.Y. 2011) (Sullivan, J.) (calling the doctrine’s future “tenuous”). Nor can the doctrine, standing alone, support an inference of scienter. The doctrine only “bolsters the strength of the inference of scienter when plaintiff has already adequately alleged facts indicating that defendants might have known their statements were false.” *Tyler v. Liz Clairborne, Inc.*, 814 F. Supp. 2d 323, 343 (S.D.N.Y. 2011); *see also In re eSpeed*, 457 F. Supp. 2d at 294.

In any event, the doctrine has no application here. “[C]ourts have required that the operation in question constitute nearly all of a company’s business before finding scienter,” and Plaintiffs do not allege, as they must, that Opdivo was “essential to [Bristol-Myers’s] survival.” *Tyler*, 814 F. Supp. 2d at 343. In fact, Plaintiffs expressly acknowledge that “CM-026’s failure did not threaten [Bristol-Myers’s] existence.” (Dkt. No. 57 at 35.)

define “strong” PD-L1 expression. Plaintiffs also cite post-study statements from Bristol-Myers officers “admitt[ing] that . . . a 5% PD-L1 expression cutoff was not ‘high.’” (*Id.* (emphasis omitted) (citing Compl. ¶ 205).) Such conduct, however, is consistent with Bristol-Myers’s current position. After all, the Plaintiffs do not allege that Bristol-Myers took the categorical position, in any prior study, that the term “strong” *compelled* a cut-off of more than 5%. And the statements from Bristol-Myers officers are similarly unhelpful. They were made in October and November of 2016 — long after the alleged misrepresentations were initially made — and they did not even employ the terms “strong” or “strongly.” (*See* Compl. ¶ 205.) Thus, these statements cannot convincingly demonstrate that the Defendants were aware of an industrywide use of the term “strong” at the time the alleged misrepresentations were made.

Finally, Plaintiffs argue that the Defendants had knowledge of industry norms “based on their knowledge that Merck . . . had defined ‘strong’ to mean PD-L1 expressions of 50% or greater” in its Keynote-024 study. (Dkt. No. 57 at 34–35.) This argument, too, founders. Plaintiffs do not allege, as they must, that the Merck study indicated that “strong” *must* mean, as a matter of industry practice, a cut-off greater than 5%. At best, the Merck study could have informed Defendants only of *Merck’s* definition of “strong” PD-L1 expression, and only in the context of a particular study.

At bottom, Plaintiffs cite no publication, guidance, communication, document, or other specific source of information that could have alerted Defendants, at the time of the alleged misrepresentations, to an industrywide consensus that “strong” PD-L1 expression was inconsistent with a 5% cut-off.⁴ *Sans* specific evidence, Plaintiffs cannot demonstrate that the

⁴ Plaintiffs also argue that Defendant Cuss’s “unexpected” departure from Bristol-Myers in March 2017 (Compl. ¶ 224) provides support for scienter (Dkt. No. 57 at 28). While resignations can sometimes support an inference of scienter, they must be “highly unusual and

Defendants used the term “strong” with a state of mind “approximating actual intent” to defraud. *Novak*, 216 F.3d at 312; *see also In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-CV-755, 2014 WL 585658, at *12 (S.D.N.Y. Feb. 14, 2014) (“Failure to follow industry standards — without more — is not itself sufficient to support scienter.”).

Accordingly, Plaintiffs’ claims under section 10(b) of the Securities Exchange Act and Rule 10b-5 fail as a matter of law.

B. Claims Under Sections 20(a) and 20A

Plaintiffs also allege control-person liability under sections 20(a) and 20A of the Securities Exchange Act. To establish a prima facie case of control-person liability, a plaintiff must successfully allege a primary violation. *See ATSI*, 493 F.3d at 108. Plaintiffs have failed to allege any primary violation; thus, they cannot establish control-person violation. Their claims under sections 20(a) and 20A are dismissed.

C. Leave to Amend

In the event of dismissal, the plaintiffs have requested leave to amend the complaint. (Dkt. No. 57 at 37.) Under Federal Rule of Civil Procedure 15(a), leave to amend shall be freely granted “when justice so requires.” Typically, district courts “grant plaintiffs at least one opportunity to plead fraud with greater specificity when they dismiss under Rule 9(b).” *ATSI*, 493 F.3d at 108 (2d Cir. 2007). Accordingly, leave to amend is granted.

suspicious” to do so. *Glaser*, 772 F. Supp. 2d at 598 (quoting *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 394 n.176 (S.D.N.Y. 2007)). Plaintiffs have pleaded no specific “facts [that] indicate that the resignation was somehow tied to the fraud alleged . . . or that defendants’ scienter was otherwise evident.” *Id.* Absent such evidence, Cuss’s departure does not suffice to support a strong inference of scienter.

III. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is GRANTED. Defendants' motion for oral argument on the motion to dismiss is DENIED as moot. Plaintiffs are granted leave to amend their complaint within thirty days of this Opinion and Order.

The Clerk of Court is directed to close the motion at Docket Numbers 51 and 64.

SO ORDERED.

Dated: September 30, 2019
New York, New York



J. PAUL OETKEN
United States District Judge